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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

DR. REDDY’S LABORATORIES INC.,

Plaintiff,

v.

AMARIN PHARMA, INC., AMARIN  
PHARMACEUTICALS IRELAND  
LIMITED, and AMARIN CORPORATION  
PLC,

Defendants.

Civil Action No. 21-10309 (ZNQ)(RLS)

(Filed Electronically)

**DEFENDANTS’ ANSWER AND AFFIRMATIVE DEFENSES TO THE COMPLAINT**

Defendants Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Limited, and Amarin Corporation plc (collectively, “Amarin”), by and through their attorneys, hereby answer and assert defenses to the claims and allegations made by Dr. Reddy’s Laboratories Inc. (“Plaintiff” or “DRL”) in the Complaint, ECF No. 1, filed on April 27, 2021 (the “Complaint”). Amarin responds based upon its knowledge as to allegations pertaining to Amarin and upon information and belief as to allegations pertaining to all other matters.

Except as specifically admitted, each factual assertion by Plaintiff is denied. Although Amarin has re-produced below the Complaint's headings and subheadings, Amarin further denies each and every factual allegation contained in the Complaint's headings or subheadings. Numbered paragraphs below correspond to the like-numbered paragraphs in the Complaint.

### **INTRODUCTION**

1. The first sentence of Paragraph 1 characterizes Plaintiff's claims, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in the first sentence of Paragraph 1. Amarin admits that Vascepa® (icosapent ethyl) is Amarin's only product in the United States (the product is sold as Vazkepa® in Europe). Amarin denies the remaining allegations in Paragraph 1.

2. Amarin admits the United States District Court for the District of Nevada entered judgment in favor of DRL in patent litigation in March 2020, which was later affirmed on appeal by the Federal Circuit. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations relating to DRL's launch readiness in Paragraph 2 and denies the allegations on that basis. The allegations relating to Amarin's conduct in the second and third sentences of Paragraph 2 reflect legal conclusions, for which no response is required. To the extent a response is required, Amarin denies these allegations.

3. Amarin admits the United States District Court for the District of Nevada entered judgment in favor of DRL in patent litigation in March 2020. Amarin further admits that it entered into a contract with KD Pharma in December 2017 and that it has issued certain purchase orders for API to KD Pharma. Amarin lacks knowledge or information sufficient to form a belief as to the remaining allegations in the first three sentences of Paragraph 3 and denies the allegations on that basis. Amarin denies the remaining allegations in Paragraph 3.

4. Amarin admits that it entered into a contract with KD Pharma in December 2017. Amarin lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 4, and denies the allegations on that basis.

5. Amarin admits that at times, it has had contractual arrangements with the companies listed in Paragraph 5 (or their predecessors). Amarin lacks knowledge or information sufficient to form a belief as to the allegations in the first two sentences and final two sentences of Paragraph 5, and denies the allegations on that basis. Amarin denies the remaining allegations in Paragraph 5.

6. Amarin admits that it may be costly to qualify and ensure quality control for API suppliers. Amarin lacks knowledge or information sufficient to form a belief as to industry practice relating to the number of API suppliers, and therefore denies the allegation in the second sentence of Paragraph 6 on that basis. Amarin denies the remaining allegations in Paragraph 6.

7. The first sentence of Paragraph 7 states a legal conclusion, for which no response is required. To the extent a response is required, Amarin denies the allegations in the first sentence of Paragraph 7. Amarin denies the remaining allegations in Paragraph 7.

8. Amarin admits that it entered into a contract with KD Pharma in December 2017. Amarin lacks knowledge or information sufficient to form a belief as to whether Plaintiff had set forth resources as described in the second sentence of Paragraph 8, and denies the allegation on that basis. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in footnote 1 of Paragraph 8, and denies those allegations on that basis. Amarin denies the remaining allegations in Paragraph 8.

9. Amarin lacks knowledge or information sufficient to form a belief regarding whether Plaintiff incurred costs to qualify an “additional alternative API supplier,” and denies the allegation on that basis. Amarin denies the remaining allegations in Paragraph 9.

10. Paragraph 10 contains no factual allegations and therefore does not require a response. To the extent a response is required, Amarin denies that Plaintiff is entitled to any relief.

### **PARTIES**

11. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations Paragraph 11, and denies those allegations on that basis.

12. Amarin admits that Amarin Pharma, Inc. is a company organized and existing under the laws of Delaware with its principal place of business in New Jersey. Amarin denies the remaining allegations in Paragraph 12.

13. Amarin admits the allegations in Paragraph 13.

14. Amarin admits that Amarin Corporation plc is a company incorporated under the laws of England and Wales with principal executive offices located in Dublin, Ireland. Amarin denies the remaining allegations in Paragraph 14.

### **JURISDICTION AND VENUE**

15. Paragraph 15 contains no factual allegations and therefore does not require a response. To the extent a response is required, Amarin denies that Plaintiff is entitled to any relief.

16. Amarin admits that it purchases icosapent ethyl API and that its products are marketed and sold in the United States. Amarin admits that drug wholesalers located in the United States purchase Vascepa. Amarin admits that patients in the United States purchase Vascepa through pharmacies and other intermediaries. The remaining allegations in Paragraph 16 reflect legal conclusions, for which no response is required. To the extent a response is required, Amarin denies the remaining allegations in Paragraph 16.

17. Amarin admits that Amarin Pharma, Inc. may be found in, transacts business in, and is headquartered in New Jersey. Amarin denies that Amarin Pharmaceuticals Ireland Limited may be found in or is headquartered in New Jersey. Amarin denies that Amarin Corporation plc may be found in or is headquartered in New Jersey. The remainder of Paragraph 17 purports to state a legal conclusion to which no response is required.

18. Paragraph 18 purports to state a legal conclusion to which no response is required.

19. Paragraph 19, in part, states legal conclusions regarding venue to which no response is required. Amarin denies the remaining allegations in Paragraph 19.

### **STATEMENT OF FACTS**

#### **I. STATUTORY AND REGULATORY BACKGROUND**

##### **A. Hatch-Waxman Framework**

20. Amarin admits that the Federal Food, Drug, and Cosmetic Act requires approval by the FDA before a company may market or sell a branded or generic pharmaceutical product in the United States. Amarin lacks knowledge or information sufficient to form a belief as to the overarching purpose of the Hatch-Waxman Act, and denies the remaining allegations in Paragraph 20 on that basis.

21. Paragraph 21 purports to describe provisions of the Hatch-Waxman Act. Amarin refers to the text of the Hatch-Waxman Act for a complete and accurate statement of its provisions and denies Plaintiff's allegations in Paragraph 21 to the extent they are inconsistent with the text of the Act.

22. Paragraph 22 purports to describe requirements of the Hatch-Waxman Act. Amarin refers to the text of the Hatch-Waxman Act for a complete and accurate statement of its provisions and denies Plaintiff's allegations in Paragraph 22 to the extent they are inconsistent with the text of the Act.

23. Paragraph 23 purports to describe provisions of the Hatch-Waxman Act. Amarin refers to the text of the Hatch-Waxman Act for a complete and accurate statement of its provisions and denies Plaintiff's allegations in Paragraph 23 to the extent they are inconsistent with the text of the Act.

24. Paragraph 24 purports to describe provisions of the Hatch-Waxman Act. Amarin refers to the text of the Hatch-Waxman Act for a complete and accurate statement of its provisions and denies Plaintiff's allegations in Paragraph 24 to the extent they are inconsistent with the text of the Act.

25. The first three sentences of Paragraph 25 purport to describe the provisions of the Hatch-Waxman Act. Amarin refers to the text of the Hatch-Waxman Act for a complete and accurate statement of its provisions and denies Plaintiff's allegations in the first three sentences of Paragraph 25 to the extent they are inconsistent with the text of the Act. The final sentence of Paragraph 25 is definitional in nature and does not require a response.

26. The first sentence of Paragraph 26 purports to describe provisions of the Hatch-Waxman Act. Amarin refers to the text of the Hatch-Waxman Act for a complete and accurate statement of its provisions and denies Plaintiff's allegations in Paragraph 26 to the extent they are inconsistent with the text of the Act. The second sentence of Paragraph 26 is definitional in nature and does not require a response. The remaining sentences of Paragraph 26 state legal conclusions and cite sources that purportedly support those conclusions, and therefore do not require a response.

#### **B. Benefits of Generic Competition**

27. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 27 and denies the allegations on that basis. Amarin refers to the Association for Accessible Medicines's study for a complete and accurate statement of its contents

and denies Plaintiff's allegation characterizing the study to the extent it is inconsistent with that source.

28. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 28 and denies the allegations on that basis.

29. Amarin admits that "payers" include health plans and pharmacy benefit managers, as alleged in the second sentence of Paragraph 29. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 29 and denies the allegations on that basis. Amarin refers to the FDA and AAM studies for complete and accurate statements of their contents and denies Plaintiff's allegations characterizing those studies to the extent they are inconsistent with those sources.

30. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 30 and denies the allegations on that basis. Amarin refers to the reports and studies referenced for complete and accurate statements of their contents and denies Plaintiff's allegations purporting to reference those reports and studies to the extent they are inconsistent with the referenced sources.

### **C. Supply and Use of API in Drug Products**

31. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 31 and on this basis denies those allegations.

32. Paragraph 32 purports to describe FDA regulatory requirements relating to DMFs. Amarin denies the allegations in Paragraph 32 to the extent the allegations are contrary to FDA regulations and practice. Indeed, as the Third Circuit has observed, "[a] manufacturer need not partner with a supplier with an active DMF during its development of an ANDA, and sometimes a drug applicant may choose to not reference a DMF in its ANDA filing at all." *See Fresenius*

*Kabi USA, LLC v. Par Sterile Prods., LLC*, 841 F. App'x 399, 404 n.12 (3d Cir. 2021). Amarin denies the remaining allegations in Paragraph 32.

33. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 33 and on this basis denies those allegations. Amarin also denies the allegations in Paragraph 33 to the extent the allegations are contrary to FDA regulations and practice. Indeed, as the Third Circuit has observed, “[a] manufacturer need not partner with a supplier with an active DMF during its development of an ANDA, and sometimes a drug applicant may choose to not reference a DMF in its ANDA filing at all.” *See Fresenius Kabi USA, LLC v. Par Sterile Prods., LLC*, 841 F. App'x 399, 404 n.12 (3d Cir. 2021).

34. Paragraph 34 purports to describe FDA regulatory requirements relating to DMFs. Amarin denies the allegations in Paragraph 34 to the extent the allegations are contrary to FDA regulations and practice. Indeed, as the Third Circuit has observed, “[a] manufacturer need not partner with a supplier with an active DMF during its development of an ANDA, and sometimes a drug applicant may choose to not reference a DMF in its ANDA filing at all.” *See Fresenius Kabi USA, LLC v. Par Sterile Prods., LLC*, 841 F. App'x 399, 404 n.12 (3d Cir. 2021).

35. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 35 and on this basis denies those allegations.

36. Amarin admits, on information and belief, that there can be significant costs involved in qualifying an API supplier. Amarin admits, on information and belief, that a manufacturer may enter into an exclusive supply contract with an API supplier where there are concerns about ensuring the adequate supply of API for a drug. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 36 and on this basis denies those allegations.



## **II. VASCEPA**

37. Amarin admits the allegations in Paragraph 37.

38. Amarin incorporates its responses to the allegations in I.A. and otherwise admits the allegations in Paragraph 38.

39. Amarin admits the allegations in Paragraph 39.

40. Amarin admits that it currently markets Vascepa in the 1g and 500mg strengths in the United States. Amarin admits that the allegations in the second sentence of Paragraph 40 reflect the Wholesale Acquisition Cost (“WAC”) price of Vascepa as of September 2020, which is a list price. With respect to the allegations in the third sentence of Paragraph 40, Amarin admits that the stated numbers reflect the WAC price for a 30-day supply of Vascepa as of the date cited in Paragraph 40, if a doctor prescribes 4g of Vascepa a day.

41. Amarin admits that the WAC price of Vascepa 1g was \$278.58 in December 2017. Amarin admits that the WAC price of Vascepa 1g was \$303.65 in November 2019. Amarin admits that the WAC price of Vascepa 1g was \$330.98 in September 2020. Amarin otherwise denies Paragraph 41. In particular, Paragraph 41 does not reflect net prices for Vascepa.

42. Amarin admits the allegations in the first sentence of Paragraph 42. With respect to the allegations in the second sentence of Paragraph 42 and the accompanying graph, Amarin refers to Amarin Corporation plc’s Form 10-K filings for a complete and accurate statement of its net product revenues by year and denies Plaintiff’s allegations to the extent they are inconsistent with those filings. With respect to the allegations in the third and fourth sentences of Paragraph 42, Amarin refers to the cited sources for a complete and accurate statement of their contents and denies Plaintiff’s allegations to the extent they are inconsistent with the cited sources and to the extent they characterize the information therein.

43. The allegations in the first two sentences of Paragraph 43 are a characterization of and reference to the cited document. Amarin refers to that document, which has nothing to do with the allegations in Paragraph 43, for a complete and accurate statement of its contents and denies Plaintiff's allegations to the extent they are inconsistent with the cited document. Amarin denies the remaining allegations in Paragraph 43.

### **III. VASCEPA PATENT LITIGATIONS AND APPROVAL OF GENERIC ICOSAPENT ETHYL DRUG PRODUCTS**

44. Amarin admits, on information and belief, the allegations in Paragraph 44.

45. The fourth sentence in Paragraph 45 purports to describe provisions in the FDCA. Amarin refers to the text of the FDCA for a complete and accurate statement of its provisions and denies Plaintiff's allegations to the extent they are inconsistent with the Act. Amarin incorporates its responses to the allegations in I.A. and otherwise admits the allegations in Paragraph 45.

46. Amarin admits, on information and belief, the allegations in the first two sentences of Paragraph 46. The allegations in the third sentence of Paragraph 46 reflect legal conclusions, for which no response is required. To the extent a response is required, Amarin denies the allegations in Paragraph 46. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the fourth and fifth sentences of Paragraph 46 and denies the allegations on that basis. Amarin denies the allegations in the final sentence of Paragraph 46.

47. Amarin admits the allegations in the first two sentences of Paragraph 47. With respect to the allegations in the third sentence of Paragraph 47, Amarin refers to the cited press release for a complete and accurate statement of its contents and denies Plaintiff's allegations to the extent they are inconsistent with the press release. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the fourth sentence of Paragraph 47

and denies the allegations on that basis. Amarin admits, on information and belief, that the FDA granted final approval for Teva's ANDA on September 11, 2020.

48. Amarin admits that it received a paragraph IV certification notice from Apotex in September 2016. Amarin admits that Apotex's ANDA contained a paragraph IV certification as to some, but not all of the patents then listed in the Orange Book for Vascepa. Amarin admits that it did not file suit against Apotex in 2016. Amarin admits that in May 2020, Amarin received a new paragraph IV certification notice reflecting that Apotex had recently amended its ANDA. Amarin admits that on June 16, 2020, Amarin Corporation plc announced a settlement agreement with Apotex. Amarin refers to the referenced press release for a complete and accurate statement of its contents and denies Plaintiff's allegations to the extent they are inconsistent with the press release. Amarin denies that the quotation in the penultimate sentence of Paragraph 48 is accurate and refers to the cited SEC filing for a complete and accurate statement of that filing's contents. On information and belief, Amarin denies the remaining allegations in Paragraph 48.

49. On information and belief, Amarin denies the allegations in Paragraph 49.

#### **IV. API FOR ICOSAPENT ETHYL DRUG PRODUCT (VASCEPA)**

50. Amarin admits the allegations in the first sentence of Paragraph 50. Amarin admits that DHA is not the API used in Vascepa. Amarin lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 50 and denies the allegations on that basis.

51. Amarin admits that API suppliers of fish oil-based drugs can switch manufacturing lines between icosapent ethyl API and omega-3-acid ethyl esters API with investment and resources. Amarin otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 51 and denies the allegations on that basis.

52. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 52 and denies the allegations on that basis. Moreover, Paragraph 52 purports to describe FDA regulatory requirements relating to DMFs. Amarin denies the allegations in Paragraph 52 to the extent the allegations are contrary to FDA regulations and practice.

**V. AMARIN'S ANTICOMPETITIVE LOCKING UP OF ICOSAPENT ETHYL API SUPPLY TO IMPEDE GENERIC COMPETITION**

53. Amarin admits that Vascepa is its sole marketed product. Amarin denies the remaining allegations in Paragraph 53.

54. The allegations in Paragraph 54 include characterizations of statements in Amarin's Form 10-K for the fiscal year ending December 31, 2014. Amarin refers to the document for a complete and accurate description of its contents. Amarin denies the characterization of these statements as describing an "anticompetitive strategy," as alleged in Paragraph 54.

55. Amarin denies the allegations in Paragraph 55.

56. Amarin denies the allegations in the first and final sentences of Paragraph 56. The remaining allegations purport to reference statements made by Amarin. Amarin refers to those sources for a complete and accurate statement of their contents and denies Plaintiff's allegations to the extent they are inconsistent with these sources and to the extent Plaintiff characterizes the information therein.

**A. Amarin Locked Up a Substantial Share of Icosapent Ethyl API Supply Through Exclusive or De Facto Exclusive Agreements**

57. Amarin denies the allegations in the first sentence of Paragraph 57. Amarin admits that Amarin Corporation plc issued a press release on December 11, 2012 and refers to the press release itself for a complete and accurate statement of its contents. Amarin denies the remaining

allegations in Paragraph 57 that purport to quote from or otherwise characterize this press release to the extent they are inconsistent with the language of the press release itself.

58. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations of the first sentence of Paragraph 58 and on this basis denies the allegations. The remaining allegations in Paragraph 58 refer to statements on certain websites. Amarin refers to the websites for a complete and accurate statement of their contents and denies Plaintiff's allegations regarding the language on those websites to the extent they are inconsistent with the cited sources.

59. Amarin admits that it terminated its agreement with the Slanmhor/DSM/Novasep consortium and entered into a supply agreement with Novasep. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's communications with API suppliers in Paragraph 59 and on this basis denies those allegations. The remaining allegations in Paragraph 59 refer to or characterize statements in referenced documents. Amarin refers to the documents themselves for a complete and accurate statement of their contents and denies Plaintiff's allegations to the extent they are inconsistent with the cited sources.

60. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the body of Paragraph 60 and denies those allegations on that basis. Footnote 25 purports to reference statements in Amarin's SEC filings. Amarin refers to the documents themselves for a complete and accurate statement of their contents and denies Plaintiff's allegation regarding the contents of Amarin's SEC filings to the extent the language of the documents is inconsistent with Plaintiff's characterization in footnote 25.

61. The first sentence of Paragraph 61 states a legal conclusion, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in the first sentence of Paragraph 61. Amarin denies that it prevented KD Pharma from supplying Plaintiff to support its commercial launch of its generic icosapent ethyl drug product. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 61 and denies those allegations on that basis.

62. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 62 and on this basis denies those allegations.

63. Amarin denies that its arrangement with BASF foreclosed BASF from supplying icosapent ethyl API to DRL, as alleged in the penultimate sentence of Paragraph 63. Amarin denies the allegations in the final sentence of Paragraph 63. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 63 and denies those allegations on that basis.

**B. Amarin Blocked the Supply of Icosapent Ethyl API to DRL Through Binding Orders With KD Pharma**

64. Amarin denies the allegations in Paragraph 64.

65. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations relating to Plaintiff's interactions with API suppliers and denies those allegations on that basis. Amarin denies the remaining allegations in Paragraph 65.

66. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 66, and denies those allegations on that basis.

67. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 67, and denies those allegations on that basis.

68. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 68, and denies those allegations on that basis.

69. Amarin admits, based on publicly available information, that there are four ANDA filers for icosapent ethyl. Amarin denies that there was interference by Amarin as alleged in the first sentence of Paragraph 69. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 69, and denies those allegations on that basis.

70. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 70, and denies those allegations on that basis.

71. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 71, and denies those allegations on that basis.

72. Amarin denies the allegations in Paragraph 72.

73. Amarin denies that it prevented KD Pharma from supplying Plaintiff. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 73, and denies those allegations on that basis.

74. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 74, and denies those allegations on that basis.

75. Amarin denies the allegations in Paragraph 75.

**VI. AMARIN'S CONDUCT IS CONTRARY TO INDUSTRY PRACTICE, HAS NO LEGITIMATE BUSINESS JUSTIFICATION, AND CAN ONLY BE EXPLAINED AS AN ANTICOMPETITIVE STRATEGY**

76. Amarin admits that it can be costly to qualify and ensure quality control at API suppliers. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 76 relating to industry practice, and denies those allegations on that basis. Amarin denies the remaining allegations in Paragraph 76.

77. Amarin denies the allegations in Paragraph 77.

78. Amarin denies the allegations in Paragraph 78.

## **VII. AMARIN'S CONDUCT HARMS DRL**

79. Amarin lacks knowledge or information sufficient to form a belief as to whether Plaintiff had set forth resources as described in the second sentence of Paragraph 79, and denies the allegation on that basis. Amarin denies the remaining allegations in Paragraph 79.

80. Amarin admits, on information and belief, that DRL has received FDA approval for its generic icosapent ethyl drug product. Amarin admits that on September 3, 2020, the Court of Appeals for the Federal Circuit affirmed the judgment entered by the United States District Court for the District of Nevada in March 2020 in favor of DRL in patent litigation against Amarin. Amarin denies that it engaged in anticompetitive conduct as alleged in the second sentence of Paragraph 80. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 80, including those in footnote 26, and denies those allegations on that basis.

81. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations relating to DRL's efforts to launch in Paragraph 81, and denies those allegations on that basis. Amarin denies the remaining allegations in Paragraph 81.

82. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations relating to DRL's purported supply relationship with the identified supplier in the first sentence of Paragraph 82, and denies those allegations on that basis. Amarin denies the remaining allegations in Paragraph 82.

83. Amarin lacks knowledge or information sufficient to form a belief as to whether Plaintiff had set forth resources as described in the second sentence of Paragraph 83, and denies the allegation on that basis. Amarin lacks knowledge or information sufficient to form a belief as



to the truth of the allegations in the third sentence of Paragraph 83, and denies those allegations on that basis. Amarin denies the remaining allegations in Paragraph 83.

84. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the third sentence of Paragraph 84, and denies those allegations on that basis. Amarin denies the remaining allegations in Paragraph 84.

#### **MARKET POWER AND RELEVANT MARKETS**

85. The allegations in Paragraph 85 reflect legal conclusions, for which no response is required. To the extent a response is required, Amarin denies the allegations in Paragraph 85.

86. Paragraph 86 states a legal conclusion to which no response is required. To the extent a response is required, Amarin denies the allegation in Paragraph 86.

87. Paragraph 87 states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 87.

88. Amarin admits that the demand for Vascepa has increased over certain periods of time. Paragraph 88 otherwise characterizes Plaintiff's claims, states legal conclusions, and is hypothetical in nature, and therefore does not require a response. To the extent a response is required, Amarin denies the remaining allegations in Paragraph 88.

89. The first sentence of Paragraph 89 characterizes Plaintiff's claims, states legal conclusions, and is hypothetical in nature, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in the first sentence of Paragraph 89. Amarin denies the allegations in the second sentence of Paragraph 89.

90. The allegations in Paragraph 90 reflect legal conclusions, for which no response is required. To the extent a response is required, Amarin denies the allegations in Paragraph 90.

91. Amarin admits that Amarin has sold Vascepa at a price in excess of Amarin's marginal cost. The remaining allegations in Paragraph 91 reflect legal conclusions, for which no

response is required. To the extent a response is required, Amarin denies the remaining allegations in Paragraph 91.

92. The allegations in Paragraph 92 reflect legal conclusions, for which no response is required. To the extent a response is required, Amarin denies the allegations in Paragraph 92.

93. The allegations in the first two sentences of Paragraph 93 reflect legal conclusions, for which no response is required. To the extent a response is required, Amarin denies the allegations in the first two sentences of Paragraph 93. With respect to the allegations in the final sentence of Paragraph 93, Amarin refers to the August 4, 2020, earnings call transcript for a complete and accurate statement of its contents and denies Plaintiff's allegations to the extent they are inconsistent with that source.

94. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations relating to Hikma's launch in the second sentence of Paragraph 94 and denies the allegations on that basis. The remaining allegations in Paragraph 94 reflect legal conclusions, for which no response is required. To the extent a response is required, Amarin denies the remaining allegations in Paragraph 94.

95. The allegations in Paragraph 95 reflect legal conclusions, for which no response is required. To the extent a response is required, Amarin denies the allegations in Paragraph 95.

96. The allegations in Paragraph 96 reflect legal conclusions, for which no response is required. To the extent a response is required, Amarin denies the allegations in Paragraph 96.

97. Amarin admits that the demand for Vascepa has increased over certain periods of time. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding the demand for Lovaza and generic omega-3-acid ethyl esters drug products in Paragraph 97, and denies those allegations on that basis. Amarin denies the remaining

allegations in Paragraph 97. In particular, the allegations do not account for the net pricing of Vascepa.

98. Amarin denies the allegations in Paragraph 98.

99. Amarin denies the allegations in Paragraph 99.

100. Amarin admits that Vascepa is a prescription medicine and is not sold directly to consumers without a prescription. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 100 given the generality of the allegations, and denies the allegations on that basis.

101. The allegation in Paragraph 101 reflects legal conclusions, for which no response is required.

#### **ANTITRUST IMPACT**

102. Paragraph 102 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 102.

103. Amarin denies the allegations in Paragraph 103.

104. Amarin denies the allegations in Paragraph 104.

105. The allegations in the first sentence of Paragraph 105 reflect legal conclusions, for which no response is required. To the extent a response is required, Amarin denies the allegations in the first sentence of Paragraph 105. Amarin lacks knowledge or information sufficient to form a belief as to whether Plaintiff had set forth resources as described in the penultimate sentence of Paragraph 105, and denies the allegation on that basis. Amarin denies the remaining allegations in Paragraph 105.

106. The allegations in Paragraph 106 reflect legal conclusions, for which no response is required. To the extent a response is required, Amarin denies the allegations in Paragraph 106.

107. The allegations in Paragraph 107 reflect legal conclusions, for which no response is required. To the extent a response is required, Amarin denies the allegations in Paragraph 107.

108. The allegations in Paragraph 108 reflect legal conclusions, for which no response is required. To the extent a response is required, Amarin denies the allegations in Paragraph 108.

**COUNT I**  
**SHERMAN ACT SECTION 2 – MONOPOLIZATION**

109. Amarin incorporates its answers to Paragraphs 1 through 108 as though fully set forth herein.

110. Paragraph 110 states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 110.

111. Paragraph 111 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 111.

112. Paragraph 112 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 112.

113. Paragraph 113 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 113.

114. The first sentence of Paragraph 114 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in the first sentence of Paragraph 114. Amarin denies the remaining allegations in Paragraph 114.

115. The first two sentences of Paragraph 115 characterize Plaintiff's claims and state legal conclusions, and therefore do not require a response. To the extent a response is required, Amarin denies the allegations in the first two sentences of Paragraph 115. Amarin denies the remaining allegations in Paragraph 115.

116. Paragraph 116 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 116.

117. Paragraph 117 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 117.

118. Paragraph 118 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 118.

119. Paragraph 119 states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 119.

120. Paragraph 120 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 120.

121. Paragraph 121 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 121.

122. Paragraph 122 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 122.

**COUNT II**  
**SHERMAN ACT SECTION 2 – ATTEMPT TO MONOPOLIZE**

123. Amarin incorporates its answers to Paragraphs 1 through 122 as though fully set forth herein.

124. Paragraph 124 states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 124.

125. Paragraph 125 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 125.

126. Paragraph 126 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 126.

127. Paragraph 127 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 127.

128. The first sentence of Paragraph 128 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in the first sentence of Paragraph 128. Amarin denies the remaining allegations in Paragraph 128.

129. Paragraph 129 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 129.

130. The first two sentences of Paragraph 130 characterize Plaintiff's claims and state legal conclusions, and therefore do not require a response. To the extent a response is required, Amarin denies the allegations in the first two sentences of Paragraph 130. Amarin denies the remaining allegations in Paragraph 130.

131. Paragraph 131 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 131.

132. Paragraph 132 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 132.

133. Paragraph 133 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 133.

134. Paragraph 134 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 134.

135. Paragraph 135 states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 135.

136. Paragraph 136 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 136.

137. Paragraph 137 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 137.

138. Paragraph 138 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 138.

**COUNT III**  
**SHERMAN ACT SECTION 1 – CONTRACT, COMBINATION, OR CONSPIRACY IN**  
**RESTRAINT OF TRADE**

139. Amarin incorporates its answers to Paragraphs 1 through 138 as though fully set forth herein.

140. Paragraph 140 states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 140.

141. Paragraph 141 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 141.

142. Paragraph 142 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 142.

143. The first sentence of Paragraph 143 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required,



Amarin denies the allegations in the first sentence of Paragraph 143. Amarin denies the remaining allegations in Paragraph 143.

144. Paragraph 144 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 144.

145. The first two sentences of Paragraph 145 characterize Plaintiff's claims and state legal conclusions, and therefore do not require a response. To the extent a response is required, Amarin denies the allegations in the first two sentences of Paragraph 145. Amarin denies the remaining allegations in Paragraph 145.

146. Paragraph 146 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 146.

147. Paragraph 147 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 147.

148. Paragraph 148 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 148.

149. Paragraph 149 states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 149.

150. Paragraph 150 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 150.

151. Paragraph 151 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 151.

152. Paragraph 152 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 152.

**COUNT IV**  
**THE NEW JERSEY ANTITRUST ACT, SECTIONS 56:9-3 AND 56:9-4**

153. Amarin incorporates its answers to Paragraphs 1 through 152 as though fully set forth herein.

154. Paragraph 154 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 154.

*Section 56:9-4, Monopolization*

155. Paragraph 155 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 155.

156. Paragraph 156 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 156.

*Section 56:9-3, Agreement in Restraint of Trade*

157. Paragraph 157 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 157.

158. Paragraph 158 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 158.

\* \* \*

159. Paragraph 159 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 159.

160. Paragraph 160 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 160.

161. Paragraph 161 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 161.

162. Paragraph 162 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 162.

**COUNT V**  
**COMMON LAW OF THE STATE OF NEW JERSEY – UNFAIR COMPETITION**

163. Amarin incorporates its answers to Paragraphs 1 through 162 as though fully set forth herein.

164. Paragraph 164 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 164.

165. Paragraph 165 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 165.

**COUNT VI**  
**COMMON LAW OF THE STATE OF NEW JERSEY – TORTIOUS INTERFERENCE**  
**WITH CONTRACT OR PROSPECTIVE ECONOMIC BENEFIT**

166. Plaintiff's tortious interference claim was dismissed in its entirety by the Court's order dated October 27, 2022, and there is accordingly no obligation to respond to these allegations.

167. Plaintiff's tortious interference claim was dismissed in its entirety by the Court's order dated October 27, 2022, and there is accordingly no obligation to respond to these allegations.

168. Plaintiff's tortious interference claim was dismissed in its entirety by the Court's order dated October 27, 2022, and there is accordingly no obligation to respond to this allegation.

169. Plaintiff's tortious interference claim was dismissed in its entirety by the Court's order dated October 27, 2022, and there is accordingly no obligation to respond to these allegations.

170. Plaintiff's tortious interference claim was dismissed in its entirety by the Court's order dated October 27, 2022, and there is accordingly no obligation to respond to these allegations.

171. Plaintiff's tortious interference claim was dismissed in its entirety by the Court's order dated October 27, 2022, and there is accordingly no obligation to respond to these allegations.

172. Plaintiff's tortious interference claim was dismissed in its entirety by the Court's order dated October 27, 2022, and there is accordingly no obligation to respond to these allegations.

173. Plaintiff's tortious interference claim was dismissed in its entirety by the Court's order dated October 27, 2022, and there is accordingly no obligation to respond to these allegations.

174. Plaintiff's tortious interference claim was dismissed in its entirety by the Court's order dated October 27, 2022, and there is accordingly no obligation to respond to these allegations.

175. Plaintiff's tortious interference claim was dismissed in its entirety by the Court's order dated October 27, 2022, and there is accordingly no obligation to respond to these allegations.

176. Plaintiff's tortious interference claim was dismissed in its entirety by the Court's order dated October 27, 2022, and there is accordingly no obligation to respond to these allegations.

177. Plaintiff's tortious interference claim was dismissed in its entirety by the Court's order dated October 27, 2022, and there is accordingly no obligation to respond to these allegations.

178. Plaintiff's tortious interference claim was dismissed in its entirety by the Court's order dated October 27, 2022, and there is accordingly no obligation to respond to these allegations.

179. Plaintiff's tortious interference claim was dismissed in its entirety by the Court's order dated October 27, 2022, and there is accordingly no obligation to respond to these allegations.

180. Plaintiff's tortious interference claim was dismissed in its entirety by the Court's order dated October 27, 2022, and there is accordingly no obligation to respond to these allegations.

181. Plaintiff's tortious interference claim was dismissed in its entirety by the Court's order dated October 27, 2022, and there is accordingly no obligation to respond to these allegations.

\* \* \*

To the extent that Amarin has not responded to any allegation in the Complaint (*see, e.g.*, paragraphs 166-181), Amarin denies that Plaintiff is entitled to any remedy or relief. The remainder of the Complaint demands a trial by jury and recites a prayer for relief to which no response is required. To the extent that a response is required, Amarin denies that Plaintiff is entitled to any remedy or relief, including those requested.

### **AFFIRMATIVE DEFENSES**

Amarin states the following defenses. In asserting these defenses, Amarin does not assume any burden of proof, persuasion, or production with respect to any issue where the applicable law places the burden upon Plaintiff. Amarin avers that some of the following defenses are actually elements of Plaintiff's claims on which Plaintiff bears the burden of proof, but pleads them as defenses out of an abundance of caution.

#### **FIRST DEFENSE**

The Complaint fails to state a claim upon which relief can be granted in whole or in part.

### **SECOND DEFENSE**

The claims in the Complaint are barred, in whole or in part, because Plaintiff suffered no damage, or its alleged damages, if any, are speculative and uncertain.

### **THIRD DEFENSE**

The claims in the Complaint are barred, in whole or in part, because Plaintiff lacks standing, antitrust standing, antitrust injury, and injury in fact.

### **FOURTH DEFENSE**

The claims in the Complaint are barred, in whole or in part, because Amarin engaged in legitimate business conduct and its conduct constitutes permissible competitive activity. For the avoidance of doubt, Amarin avers that Plaintiff bears the burden of proof on these issues.

### **FIFTH DEFENSE**

The claims in the Complaint are barred, in whole or in part, by Plaintiff's failure to mitigate damages.

### **SIXTH DEFENSE**

The claims in the Complaint are barred, in whole or in part, because the injuries alleged by Plaintiff, to the extent any exist, were caused, in whole or in part, not by Defendants, but by acts or omissions of Plaintiff. For the avoidance of doubt, Amarin avers that Plaintiff bears the burden of proof on these issues.

### **SEVENTH DEFENSE**

The claims in the Complaint are barred, in whole or in part, because none of Amarin's challenged actions or omissions substantially lessened competition within any properly defined market. For the avoidance of doubt, Amarin avers that Plaintiff bears the burden of proof on these issues.

### **EIGHTH DEFENSE**

The claims in the Complaint are barred, in whole or in part, because the challenged conduct has procompetitive justifications that outweigh any alleged anticompetitive effect. For the avoidance of doubt, Amarin avers that Plaintiff bears the burden of proof on these issues.

### **PRAYER FOR RELIEF**

Based upon the foregoing, Amarin prays that (a) judgment be entered dismissing the Complaint on the merits, in its entirety and with prejudice, and (b) this Court grant it such other relief as it deems just and appropriate including costs and reasonable legal fees.

### **DEFENDANTS' DEMAND FOR JURY TRIAL**

Amarin requests a trial by jury, under Fed. R. Civ. P. 38, for all issues triable of right by a jury.



Dated: December 6, 2022

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